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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,119	10/04/2004	Linda Diehl	470-045183	4799

7590 04/30/2008

Webb Ziesenheim Logsdon
Orkin & Hanson
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,119	DIEHL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 01/10/2008, has been entered.
Claims 13-15 and 17-21 have been amended.
Claim 26 has been canceled. Claims 1-12 have been canceled previously.

Claims 13-25 are pending.

Applicant's election with traverse of the species (A) treating a tumor in the Election With Traverse, filed 06/08/2007, has been acknowledged.

Claims 13-25 are under consideration as they read on the elected invention of species (A) tumor (and not infectious agent) in the instant application.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's amendment, filed 01/10/2008.

The rejections of record can be found in the previous Office Action, mailed 09/10/2007.

3. Priority Issues.

As indicated previously, the following of record is reiterated for convenience.

The filing date of the instant claims is deemed to be the filing date of PCT/NL03/00254, filed 04/04/2003.

Priority applications USSN 010/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999 does not support all of the current claim limitations of the instant application.

If applicant desires priority prior to 04/04/2003, applicant is invited to point out and provide documentary support for the priority of the instant claims.
Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph.

A) The recitation of "for induction of systemic T cell immunity against an antigen of the tumor or infectious agent" (versus activating CTLs) appears to receive a priority date back to PCT/NL03/00254, filed 04/04/2003; but not to priority applications USSN 010/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999.

B) The recitation of "wherein the treatment does not comprise immunization with an antigen of the tumor or infectious agent" appears to receive a priority date back to the PCT/NL03/00254, filed 04/04/2003; but not to priority applications USSN 010/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999.

C) The recitation of "infectious agent" appears to receive a priority date back to PCT/NL03/00254, filed 04/04/2003; but not to priority applications USSN 010/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999.

While USSN 010/115,620, filed 04/04/2002, appears to provide written support for "infectious virus", USSN 010/115,620 does not provide for the written support for the broader recitation of "infectious agent" of the instant application.

D) The recitation of "agonistic anti-CD40 antibody" appears to receive a priority back to priority application USSN 010/115,620, filed 04/04/2002; but not to USSN 09/316,935, filed 05/22/1999.

E) The recitation of "tumor-specific antigen" appears to receive a priority date back to PCT/NL03/00254, filed 04/04/2003; but not to priority applications USSN 010/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999.

F) The recitation of "intra-tumoral" (versus "directly to the tumor") appears to receive a priority date back to PCT/NL03/00254, filed 04/04/2003; but not to priority applications USSN 010/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999.

Given the number of continuation-in-part applications, applicant is invited to clarify the support under 35 USC 112, first paragraph, for the priority of the instant claims in the lineage of priority documents for establishing the record for clarity.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Again, if applicant desires priority prior to dates indicated above or back to the asserted priority dates for the instant claims; again, applicant is invited to point out and provide documentary support for the priority of the instant claims.

In addition, applicant is invited to consider reciting "limitations" clearly supported by the earliest priority document(s) upon which applicant wants to rely, rather than reciting "limitations" that may be similar but not the same as clearly provided by the written description of the instant and priority documents.

4. If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

Again, applicant should amend the first page of the specification to indicate the status and relationship of the priority documents.

5. Again, the Title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

6. Upon reconsideration of applicant's amended claims, filed 01/10/2008, the previous rejections under 35 U.S.C. § 112, second paragraph, have been withdrawn.

7. Upon reconsideration of applicant's amended claims, filed 01/10/2008, the previous rejection under 35 U.S.C. 112, first paragraph, written description with respect to the recitation of "CD40 receptor" has been withdrawn.

8. Upon reconsideration of applicant's amended claims, filed 01/10/2008, the previous rejection under 35 U.S.C. 112, first paragraph, enablement with respect to the recitation of "V_H, V_L, and Fd fragments" has been withdrawn.

9. Upon reconsideration of applicant's arguments in conjunction with the recitation of "wherein the treatment does not comprise immunization with an antigen of the tumor", the previous rejection under 35 U.S.C. § 102(b) as being anticipated Melief et al. (WO 99/61065) (1449) has been withdrawn.

10. Claims 13-25 are rejected under 35 U.S.C. § 102(b) as being anticipated Siegall et al. (US 2004/0235074 A1) (see entire document) essentially for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Applicants respectfully traverse this rejection for the following reasons. Siegall shows that the use of a specific anti-CD40 antibody seems to induce B cell proliferation in viO'o in peripheral B cells expressing CD40 (example 7.2.2). However, this example only shows that this specific antibody is able to stimulate B cells in vitro.

Siegall further shows that growth reduction of a human tumor is induced in a SCID mouse model using the same human anti CD40 antibody (example 8). One having ordinary skill in the art is aware that an SCID mouse does not have any T and B cells. Since the anti-CD40 antibody used is a human antibody, it can only induce a growth reduction of the tumor by binding a human CD40 molecule expressed on the tumor itself. Therefore, this experiment shown in Siegall does not demonstrate any in vivo activation of T or B cells to exert an anti-tumor effect. Accordingly, Siegall fails to disclose that a systemic T cell immunity can be induced in vivo by an anti-CD40 antibody to exert an anti-tumor, let alone an anti-infectious agent.

In contrast to applicant's assertions focusing on the induction of B cell proliferation and treatment in a SCID mouse model,

applicant ignores the clear teachings of Siegall et al. of treating cancer and immune disorders as well as activating/augmenting the immune response of a patient with agonistic anti-CD40 antibodies (e.g., see entire document, including Therapeutic Uses, Effective Doses, Formulations on pages 12-14 and Claims).

Also, in contrast to applicant's focus on the Examples, Siegall et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1) as pointed out previously.

Also, as pointed out previously, Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

The following is reiterated for applicant's convenience.

Siegall et al. teach methods of using agonistic anti-CD40 antibodies, which enhance CD40L-mediated interactions, including chimeric and humanized, including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Section 5.6 mAb S2C6 Antibody Derivatives in paragraphs [0081] – [0091]) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention and Section 5.9 Therapeutic Uses, Section 5.9.1 Effective Dose and Section 5.9.2 Formulations on pages 12-14 and Claims). Here in Section 5.9.2 Formulations, modes of administration via injection and oral administration.

Siegall et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1).

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

Although the reference does not teach tumor-specific antigens per se, given the Malignancies set forth in Table 1 on pages 12-13, tumor-specific antigens would be inherent to the described tumors.

Although the reference is silent about the induction of "systemic T cell immunity against an antigen of the tumor", "wherein the treatment does not comprise immunization with an antigen of the tumor", "tumor-specific antigen" per se,
it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991).
Also, see M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant's arguments have not been found persuasive.

11. Claims 13-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Siegall et al. (US 2004/0235074 A1) in view of Melief et al. (WO 99/61065) (1449) essentially for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Applicants respectfully request clarification of this rejection. The Office Action fails to cite any motivation for the combination of Siegall with Melief. The Office Action also fails to state why such a combination would hypothetically disclose the present invention.

In any event, Applicants traverse this rejection for the following reasons. With respect to Siegall, one having ordinary skill in the art would not have been motivated to use an anti-CD40 antibody to induce a systemic T cell immunity to obtain an anti-tumor response in vivo. As discussed in detail above, Siegall only shows an in vitro induced- proliferation of B cells using such an antibody. There is no indication in Siegall that this antibody could be used to induce either an anti-tumor T cell response or an anti-tumor B cell response in vivo. Furthermore, one having ordinary skill in the art knows that when a B cell response is induced, it does not necessarily mean that "inherently" a T cell response will also be induced. On the contrary, T and B cells are each induced by a distinct mechanism. Therefore, the existence of an activation of B cells in vitro might even be seen as teaching away from the present invention.

Furthermore, one having ordinary skill in the art would not be motivated to combine Siegall with Melief as Melief teaches away from this combination. In particular, as noted above, Melief teaches that a peptide is needed in addition to an anti-CD40 antibody. Accordingly, even if such a combination of references is valid, one would not arrive at the present invention because Melief specifically teaches the use of the anti-CD40 antibody with a peptide.

Applicant's arguments and the examiner's rebuttal concerning the teachings of Siegall et al. are essentially the same as above and reiterated herein for applicant's convenience.

In contrast to applicant's assertions focusing on the induction of B cell proliferation and treatment in a SCID mouse model,
applicant ignores the clear teachings of Siegall et al. of treating cancer and immune disorders as well as activating/augmenting the immune response of a patient with agonistic anti-CD40 antibodies (e.g., see entire document, including Therapeutic Uses, Effective Doses, Formulations on pages 12-14 and Claims).

Also, in contrast to applicant's focus on the Examples, Siegall et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1) as pointed out previously.

Also, as pointed out previously, Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Contrary to appellant's argument that Melief et al. teach away from the claimed invention, it is noted that a prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the appellant." See In re Haruna, 249 F.3d 1327, 58USPQ2d 1517 (Fed. Cir. 2001).

Also, in contrast to applicant's assertions; disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi USPQ 423 (CCPA 1971). A known or obvious composition does not patentable simply because it has been described as somewhat inferior to some other product for the same use. See In re Gurley 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See MPEP 2123.

General skepticism of those in the art -- not amounting to teaching away -- is also "relevant and persuasive evidence" of nonobviousness. Gillette Co. v. S.C. Johnson & Son, Inc. , 919 F.2d 720, 726, 16 USPQ2d 1923, 1929 (Fed. Cir. 1990). In effect, "teaching away" is a more pointed and probative form of skepticism expressed in the prior art. In any case, the presence of either of these indicia gives insight into the question of obviousness.

Also, with respect to applicant's assertions of lack of motivation, applicant is reminded that the prior art references must be considered in their entirety.

Again, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the combination of the prior art disclosure in motivating the ordinary artisan to administer anti-CD40 antibodies to patients with tumors.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to treat patients with tumors with agents that could enhance the immune system or that could treat tumors,
Incorporating agonistic anti-CD40 antibodies in therapeutic regimens with tumor-bearing patients would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such methods to effectively treat tumors in a subject.

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Siegall et al. teach methods of using agonistic anti-CD40 antibodies, which enhance CD40L-mediated interactions, including chimeric and humanized, including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Section 5.6 mAb S2C6 Antibody Derivatives in paragraphs [0081] – [0091]) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention and Section 5.9 Therapeutic Uses, Section 5.9.1 Effective Dose and Section 5.9.2 Formulations on pages 12-14 and Claims). Here in Section 5.9.2 Formulations, modes of administration via injection and oral administration.

Siegall et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1)

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40,
including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

Although the reference does not teach tumor-specific antigens per se, given the Malignancies set forth in Table 1 on pages 12-13, tumor-specific antigens would be inherent to the described tumors.

In addition, Melief et al. teach that CD40 ligation can provide an already protective tumor-specific vaccine with the capacity to induce therapeutic CTL immunity in tumor bearing individuals (e.g., see page 5, paragraph 2);
the prior art teaches the induction of T cell immunity to tumor specific antigen wherein the treatment does not comprise immunization with an antigen of the tumor,
since the individual has already been treated with a tumor specific antigen vaccine and the treatment does not require further immunization with the tumor specific antigen.
the treatment for tumor specific antigens,

Siegall et al. does not teach the known applicability of using DEIMMUNISED and human antibodies as therapeutic antibodies at the time the invention was made.

Melief et al. teach methods of using dendritic cell activating anti-CD40 antibodies, including chimeric, DEIMMUNISED, humanized and human antibodies, including antigen-binding fragments encompassed by the claimed invention (e.g., see pages 4 and 9-12 and Claims) for the treatment of cancer (e.g., see Summary of the Invention on pages 4-5 and Claims). The Background of the Invention and Summary of the Invention teach the use of such anti-CD40 antibodies to activate dendritic cells and CTLs to act against tumor cells and cancer.

Although Siegall et al. does not teach administering the anti-CD40 antibodies intra-tumorally, Melief et al. teach administration directly to the tumor in addition to the known and conventional modes of administration via injection and oral administration or (e.g., see page 12, paragraph 2 and Claims, including Claim 7 of Melief et al.).

Melief et al. teach the stimulation via CD40:CD40L, wherein the CD40L was the known receptor for CD40 at the time the invention was made (e.g., see Background of the Invention and Summary of the Invention).

Given the teaching that CD40 ligation can provide an already protective tumor-specific vaccine with the capacity to induce therapeutic CTL immunity in tumor bearing individuals (e.g., see page 5, paragraph 2);
the prior art teaches the induction of T cell immunity to tumor specific antigen wherein the treatment does not comprise immunization with an antigen of the tumor,
since the individual has already been treated with a tumor specific antigen vaccine and the treatment does not require further immunization with the tumor specific antigen.

Also, it is noted that methods of administration encompass a result effective variable. It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs, Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious). As the claimed methods of administration were known to the ordinary artisan, it would have been obvious to optimize both the mode of administration as well as dosage amounts.

Depending on the needs of the patient and the nature of the therapeutic endpoint, one of ordinary skill in the art at the time the invention was made would have been motivated to provide antagonistic antibodies via multiple modes of administration, including the intravenous, subcutaneous and intramuscular routes of administration as known and practiced at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
Art Unit 1644
April 23, 2008